

INITIAL DISCUSSION FOR ISSUE PAPER

Proposed Regulatory Changes to Application of Tax to Dental Bone Screws and Implants

Regulation 1591, Medicines and Medical Devices

Issue

Should Regulation 1591, *Medicines and Medical Devices*, be amended to clarify the application of tax to sales of dental bone screws and implants?

Background

On March 7, 2000, an interested party, Ernst & Young LLP [“industry”], submitted a proposal to amend subdivision (b)(5) of Regulation 1591 to include dental bone screws and implants within the definition of prosthetic devices that are considered medicines under section 6369 of the Revenue and Taxation Code (RTC). By letter dated April 13, 2000, industry submitted further information to show that dental implants are used for the treatment and prevention of disease and, in addition to its proposal to amend subdivision (b)(5) of the regulation. In that letter, industry also proposes that subdivision (b)(2) be amended to include dental bone screws within the definition of medicine under RTC section 6359 in addition to amending subdivision (b)(5).

In response to the interested party meeting on April 19, 2000, industry provided a follow up letter on May 12, 2000, with seven articles showing that dental bone screws and implants are used for the treatment and prevention of disease.

A submission was also received from the California Dental Association on May 9, 2000, supporting the proposal to classify dental bone screws and implants as an exempt medicine under RTC section 6369.

Current Application of Tax

Currently, dental bone screws are not specifically covered in the regulation. Staff had previously concluded that dental bone screws were not medicines under RTC section 6369 and Regulation 1591 for two reasons. First, staff regarded the exclusion of dental prostheses set forth in subdivision (c)(4) of RTC section 6369 as encompassing dental bone screws. Second, in order for a bone screw to qualify as a medicine under RTC section 6369(c)(2), it must assist the functioning of any natural organ, artery, vein, or limb. Since dental bone screws are implanted in the jawbone, staff had regarded them as not assisting the natural function of an organ, artery, vein, or limb. Other dental items are covered in Regulation 1591. Dental implants are dental prosthetic devices, and dental prosthesis are specifically excluded from the definition of medicine in subdivision (b)(5) of Regulation 1591, as required by subdivision (c)(4) of RTC section 6369.

History of Regulation 1591 – Dental Items and Bone Screws

Regulation 1591 was first enacted in 1962 (under Ruling No. 22) to interpret and explain the application of tax to sales of medicines, under RTC Section 6369, for the diagnosis, cure,

INITIAL DISCUSSION FOR ISSUE PAPER

Proposed Regulatory Changes to Application of Tax to Dental Bone Screws and Implants

Regulation 1591, Medicines and Medical Devices

treatment, or prevention of disease of a human being. In 1970, Assembly Bill 403 (Hayes and Britschgi), added dental prescription medicines to the class of medicines the sale and use of which are exempt from sales and use tax under section 6369. The second part of the bill expanded the definition of medicines to include sutures, whether permanently implanted, bone screws, bone pins, pacemakers, and other articles permanently implanted in the body. This change clarified the distinction between prosthetic devices that are not “medicines” under the RTC, from items such as bone screws that are medicines.

In 1977, Senate Bill 588 excluded dentures from the definition of “medicines.” In 1978, Senate Bill 103 added crowns, caps, inlays and other dental prosthetic materials and devices and orthodontic appliances to the items excluded from the definition of “medicines.”

Discussion

There is no doubt that dental bone screws and implants are used in the treatment and prevention of disease, as shown by the articles provided by industry. The articles are not attached to this paper since staff agrees with the medical benefits dental implants provide. Industry believes that, on this basis, dental bone screws and implants should be properly classified as medicines under the statute. However, the critical question is not whether the items are used in the treatment and prevention of disease, as is the case of virtually any medical device, but rather whether the item was intended by the Legislature to be covered by the statutory exemption.

Upon further review, staff believes that its prior conclusion with respect to *dental bone screws* (as opposed to dental implants) may be incorrect. An important aspect of the staff’s view was based on the sequence of the Legislature’s adoption of the statute adding bone screws followed by its adoption of a statute specifically excluding “dental prosthetic materials and devices” from the definition of medicine for purposes of the exemption. Since staff regarded dental bone screws as dental prosthetic devices, staff concluded that the Legislature had instructed that these be excluded from the exemption. Staff is now of the view that the Legislature’s inclusion of “bone screws” within the definition of medicines refers to *all* bone screws; if the Legislature had intended to exclude bone screws used for dental purposes, it could have and surely would have been explicit in doing so to avoid the very ambiguity considered herein. Thus, staff now believes that, although exemptions must be construed strictly, it is appropriate to regard the exclusion of “dental prosthetic materials and devices” as not detracting from the inclusion of bone screws, even if those bone screws are used for dental purposes.

The other aspect of staff’s prior view was based on the conclusion that dental bone screws are not used to assist the functioning of any natural organ, artery, vein, or limb as required by subdivision (c)(2) of RTC section 6369. Staff now believes that this interpretation is too narrow. For example, a bone screw used in a rib. Since the rib is not a limb, in order for the bone screw to be regarded as a medicine, the rib must be part of an organ assisted by the insertion of the

INITIAL DISCUSSION FOR ISSUE PAPER

Proposed Regulatory Changes to Application of Tax to Dental Bone Screws and Implants

Regulation 1591, Medicines and Medical Devices

bone screw. Since staff agrees that a bone screw used in a rib is a medicine, staff necessarily agrees that the rib is part of an organ. That organ must be the skeleton. The jaw is part of the skeleton, and thus is part of an organ. Accordingly, staff now believes that use of bone screws in the jaw does not disqualify them from coming within subdivision (c)(2) of RTC section 6369.

Staff believes that the other items at issue cannot be regarded as medicines. Industry's proposal to amend subdivision (b)(5) of Regulation 1591 to include "dental bone screws and implants" within those prosthetic devices that can be considered medicines is directly contrary to the explicit statutory language of RTC section 6369. That section excludes dental prosthetic devices from the definition of medicine. The only basis for regarding any of the items at issue here as medicines under RTC section 6369 is that "bone screws" are specifically included in items qualifying as medicines. While staff now believes that it is appropriate to treat dental bone screws the same as other bone screws for purposes of the exemption, there is no basis for defining dental implants (which are dental prosthetics) as being included within the definition of medicine when dental prosthetics are specifically excluded therefrom by statute.

Summary

Staff recommends amending subdivision (b)(2) of Regulation 1591 to specifically include dental bone screws within the definition of medicine. Staff recommends not amending subdivision (b)(5) of Regulation 1591 as proposed by industry since neither dental bone screws nor dental implants qualify as prosthetic devices which are included within the definition of medicine. Rather, staff recommends amending subdivision (b)(5) to specifically include dental implants and appurtenances in the exclusions listed in subdivision (b)(5) for purposes of clarification.

Prepared by the Program Planning Division, Sales and Use Tax Department

Current as of 5/26/2000

dhl: 5/26/00

REGULATION 1591. MEDICINES AND MEDICAL DEVICES

Reference: Sections 6006 and 6369 Revenue and Taxation Code.

(a) Definitions.

(1) Administer. “Administer” means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) Dispense.. “Dispense” means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) Furnish. “Furnish” means to supply by any means, by sale or otherwise.

(4) Health Facility. “Health Facility” as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, which provides that:

“As used in this chapter ‘health facility’ means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer....”

(5) Pharmacist. “Pharmacist” means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of section 4200 of the Business and Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.”

(6) Pharmacy. “Pharmacy” means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of section 4037 of the Business and Professions Code.

(7) Prescription. “Prescription” means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state *and* given individually for the person or persons for whom ordered. The order must include all of the following:

Exhibit 1

- (A) The name or names and address of the patient or patients.
 - (B) The name and quantity of the drug or device prescribed and the directions for use.
 - (C) The date of issue.
 - (D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.
 - (E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.
 - (F) If in writing, signed by the prescriber issuing the order.
- (8) Physicians, Dentists, Optometrists, and Podiatrists. “Physicians,” “dentists,” “optometrists,” and “podiatrists” are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. “Physician” means and includes any person holding a valid and unrevoked physician’s and surgeon’s certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to section 2065 of the Business and Professions Code, when acting within the scope of that section.
- (9) Medicines. “Medicines” means any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.
- (b) “Medicines.” The term “medicines” means and includes the following items:
- (1) Preparations and Similar Substances. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use- qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).
- “Preparations” and similar “substances” include, but are not limited to, drugs such as penicillin, and other antibiotics, “dangerous drugs” (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines.
- (2) Permanently Implanted Articles. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not

apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, including dental bone screws; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; defibrillator programmer and high voltage stimulator used with an implanted defibrillator; and tissue and breast expanders. The sale or use of these items is subject to tax.

(3) Artificial Limbs and Eyes. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) Orthodic Devices. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1)

Orthotic devices worn on the body of the person includes, but are ~~is~~ not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and

Exhibit 1

garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

- (A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;
- (B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or
- (C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) Prosthetic Devices. Prosthetic devices and their replacements parts, designed to be worn on or in the-patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, dental implants and appurtenances, and other

Exhibit 1

dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) Drug Infusion Devices. Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) Exclusions from the Definition of “Medicines.”

Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(6)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. “Medicines” does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (Division 9, commencing with section 23000, of the Business and Professions Code).

(d) Application of Tax – In General.

Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

Exhibit 1

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) Specific Tax Applications.

(1) Prescriptions. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) Licensed Physician, Dentist or Podiatrist. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge-to his or her patients for the medicines furnished.

(3) Health Facility Tax does not apply to sales-of medicines by a health facility (as defined in subdivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) Pharmaceutical Manufacturer or Distributor. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The

exemption from tax includes the costs of the materials used to package the “sample” medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the “samples” whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration’s drug development and approval process. “Clinical trial medicines” are substances or preparations approved as “Investigational New Drugs” by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. “Clinical trial medicines” do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) Antimicrobial Agents Used by Hospital Personnel. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient’s treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) Vitamins, Minerals, Herbs, and Other Such Supplements. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) Diagnostic Substances, Test Kits, and Equipment. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body (“in vitro”) in an artificial

environment. They are not administered in the living body (“in vivo”). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) Insurance Payments

(1) Medical Insurance and Medi-Cal. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) Medicare

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) Employer Medical Contracts. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) Records.

Exhibit 1

Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are “deemed to be dispensed on prescription” within the meaning of Revenue and Taxation Code section 6369:

Name of purchaser
Name of doctor
Date of sale
Item sold
The sale price

(2) “Double Deduction” Unauthorized. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

History: Effective January 1, 1962.

Amended May 16, 1962.

Amended September 18, 1963, effective as amended September 20, 1963.

Amended and renumbered December 10, 1969, effective January 11, 1970.

Amended May 4, 1971, effective July 1, 1971.

Amended September 14, 1972, effective September 15, 1972.

Amended January 18, 1973, effective January 26, 1973.

Amended October 20, 1977, effective October 28, 1977. Changed to conform to Revenue and Taxation Code Sections 6369 and 6369.2. Added orthotic and prosthetic devices to definition of “medicines”; excluded “dentures” from the definition of “medicines”; added mammary prostheses and ostomy appliances to items to be dispensed on prescription; added wheelchairs, crutches, canes, quad canes and walkers as exempt items. Changed all references to the term “hospital” to “health facility” as defined in Section 1250 of the Health and Safety Code.

Amended March 1, 1978, effective April 29, 1978. In (b) (4) added list of specific orthotic devices; in (b) (5) added list of prosthetic devices; in (c) (1), (2) and (3) included specific items excluded from the term “medicines”; in (g) made grammatical change; in (i) added list of specific items to be included under this section; in (j) added leases to

Exhibit 1

transactions to which tax does not apply and provided that tax applies to all replacement parts; in (m) deleted references to former Section 280 of Title 17, California Administrative Code, and added (1) specifying acceptable documentation for exempt sales and (3) suggesting use of Regulation 1667 "Exemption Certificates."

Amended July 27, 1978, effective July 31, 1978. In (b) (5) deleted dental crowns, caps and inlays from definition of "medicines"; in (c) (1) added crowns, caps, inlays and other dental prosthetic materials and devices to exclusions from term "medicines"; in (c) (2) added orthodontic appliances to exclusions from term "medicines"; in (i) provided that orthotic and prosthetic devices shall be deemed to be dispensed on prescription; in (k) exempted replacement parts for wheelchairs, crutches, canes, quad canes and walkers from tax.

Amended September 27, 1978, effective November 18, 1978. In (b) (5) added intraocular lenses and ear implants; moved general exclusionary language from (c) (3) to (c); to (c) (2) added reference to footnote 3; and added reference to orthodontic appliances and devices to footnote 3.

Amended September 26, 1979, effective November 16, 1979. Adds (1); reletters former (1) and following subsection.

Amended July 27, 1983, effective November 17, 1983. Added subdivision (b) (7); changed reference in first sentence of (c) from (b) (6) to (b) (7). Added "and, on or after January 1, 1983, "insulin syringes" to subdivision (h) and added subdivision (m); relettered former subdivisions (m), (n), (o) to (n), (o), (p).

Amended August 24, 1988, effective October 7, 1989. In subdivision (b) (4) added provisions to include "custom made biomechanical foot orthoses" within the definition of the term medicines.

Amended October 26, 1993, effective February 17, 1994. Amended subdivision (k) to provide the exemption from tax for white canes used by the legally blind; removed obsolete dates in subdivisions (b) (4), (b) (7), (h), and (m).

Amended June 27, 1996, effective August 23, 1996. Amended subdivisions (b)(4) & (5) to correct spelling errors; added new subdivision (n), and renumbered former subdivisions (n), (o), and (p) as (o), (p), and (q), respectively.

Amended November 19, 1996, effective December 19, 1996. Added new (a)(7) to incorporate provisions of Assembly Bill 3836 (Chapter 857, Statutes of 1994).

Amended August 10, 1998, effective October 17, 1998. Amended subdivisions (a)(6), (d), (e) to reflect changes in sections of the Business and Professions Code; corrected spelling errors in subdivisions (b)(4)(A) and (b)(5); changed "which" to "that" in subdivision (g); removed obsolete date in subdivision (k); amended subdivisions (l)(1) and (l)(3)(B) to reflect changes in sections of the California Vehicle Code.

Amended November 18, 1999, effective March 10, 2000. Deleted the references to sections 6369.1, 6369.2, 6369.4 and 6369.5 for those parts of former Regulation 1591 that were reprogrammed as Regulations 1591.1, 1591.2, 1591.3 and 1591.4. Subdivision (a) formerly titled "Generally" was deleted and replaced with new subdivision (a) titled "Definitions." Subdivision (b) retitled "Medicines;" also added the phrase "the following items" to the end of the first sentence. Subdivision (b)(1)

Exhibit 1

added new title "Preparations and Similar Substances" and amended language for clarity; new sentence added to the end of the first paragraph; also added new unnumbered paragraph. Subdivision (b)(2) added new title "Permanently Implanted Articles;" amended the first sentence for clarity; former second sentence deleted; new second and third sentences added; also two new unnumbered paragraphs added. Subdivision (b)(3) added new title "Artificial Limbs and Eyes;" amended the first sentence for clarity; new last sentence added. Subdivision (b)(4) added new title "Orthotic Devices;" amended first sentence for clarity; deleted the part of the former first sentence after the semi-colon; deleted former second, third and fourth sentences and replaced them with new sentences which define when orthotic devices qualify as exempt medicines; examples (A), (B) and (C) consisting of items which do not qualify as custom-made biomechanical foot orthosis, were moved to become the new third unnumbered paragraph; the former second unnumbered paragraph, becomes the first unnumbered paragraph and is amended for clarity. new last sentence added; also new second unnumbered paragraph added. Subdivision (b)(5), added the title "Prosthetic Devices;" deleted the phrase "other ... devices" from the first sentence and included its content in a new third unnumbered paragraph; added the phrase "are ... 6369(c)(4)" to the end of the first sentence; also added new second, third and fourth sentences to the first paragraph; and new second and third unnumbered paragraphs added. Subdivision (b)(6) deleted and prior content moved to subdivision (b)(3). Former subdivision (b)(7) renumbered (b)(6) and retitled "Drug Infusion Devices;" added the phrases "a drug on ... volume" and "qualify ... section 6369(c)(6)." to the first sentence; also added a new second sentence. Subdivision (c), deleted the word "Term" in the title and replaced it with the phrase "the Definition of;" In the first paragraph deleted the cross-reference "(b)(2) through (b)(7) above" and replaced it with "subdivision (b)" in the first sentence; remainder of first sentence amended for clarity; also new second sentence added. In subdivision (c)(1) added cross-reference to new subdivision (b)(6). Subdivision (d) formerly titled "Who is a Registered Pharmacist" was deleted and its content transferred to new subdivision (a)(5) titled "Pharmacist." The language of former subdivision (a) "General" was moved to new subdivision (d) titled "Application of Tax – In General;" New subdivisions (d)(1) through (d)(6) added. Subdivision (e) formerly titled "What Constitutes a Prescription" deleted and most of its content repromulgated as subdivision (a)(7). New subdivision (e) retitled "Specific Tax Applications;" New subdivision (e)(1) added, detailing who can write a prescription. Subdivision (f) "Licensed Physician, Dentist or Podiatrist" renumbered as subdivision (e)(2). Subdivision (g) "Health Facility" renumbered as new subdivision (e)(3); the first sentence up to the colon deleted; also deleted the first unnumbered paragraph in former subdivision (g) and repromulgated it as (a)(4); and added the phrase "by a health facility" and a reference to (a)(4) in the first sentence. New subdivision (e)(4) added. New subdivision (e)(5) added to conform the regulation to the decision in *Purdue Frederick Co. v. SBE* (1990) 218 Cal.App.3d 1021 and to codify in regulatory form interpretations of the case now contained in annotations. New subdivisions (e)(6) and (e)(7) added. Former subdivisions (h) through (n) deleted. Former subdivision (o) redesignated as subdivision (f) "Insurance Payments." New subdivision (f)(1) titled "Medical Insurance and Medi-Cal" added, using the language of former subdivision

Exhibit 1

(o). New subdivision (f)(2) titled "Medicare" added. Former subdivision (p) relettered (f)(3). Former subdivision (q) renamed (g); also added the phrase "in which their sale or use is" to (g)(3).